
REMARKS

Applicant has reviewed and considered the Office Action dated July 2, 2003 and the references cited therein. In response thereto, claims 10-14, 19, 22-25, and 27-36, which were withdrawn from consideration are now canceled without prejudice or disclaimer. Claims 1, 17, and 26 are amended. As a result, claims 1-2, 6-9, 15-18, 20-21, and 26 are pending in the present application.

Rejection under 35 U.S.C. § 102

Claims 1, 2, 6-9, 15-18, 20-21 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 3,759,425 (Lee). Applicant respectfully traverses the rejection for the following reasons.

Claim 1 recites a device for metered administration of a fluid drug to an injection area of a patient comprising a container having a piston for administering said fluid drug through an outlet of said container; a catheter connected to the outlet of said container, the catheter having a front end facing away from the outlet and being connected to an injection needle; a valve positioned between the outlet and the injection needle in a flow cross section of the fluid drug, the valve having an inlet end adjacent the outlet and an outlet end adjacent the injection needle, wherein the valve is designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column, which is a pressure at the bottom of the fluid column created by the fluid column when the container and catheter are filled and the container is suspended above the injection site to a height allowed by the catheter when extended; and a driven member driving the piston towards the catheter, wherein the piston is only held in the container by frictional forces of a side wall at the container, such that advancing movement of the driven member and the piston is controlled to administer the fluid drug in a dosed manner through the outlet.

Lee discloses a piston valve syringe gun. More particularly, Lee discloses a syringe gun suitable for dispensing liquid having a barrel (24), the rear end of which is located within a recess in a base member having an internally screw-threaded bore (27) concentric with and of less diameter than the recess (25) and the interior of the barrel (24). Rotatably disposed within the bore (27) is an externally screw-threaded sleeve (28) within which is slidably located a piston-rod (29) having an axial bore (30), as shown in Figures 5-8. Accordingly, Lee discloses

that the piston is held in the barrel via an interlocking mechanism. Claim 1 is now amended to further recite that the piston is held in the container by frictional forces between it and the side wall of the container, such that advancing movement of the driven member and the piston is controlled to discharge the fluid drug in a dosed manner through the outlet. Accordingly, there is no interlocking or material connection between the piston and the driven member. Support can be found on page 8, lines 1-5 of the present specification.

Further, as disclosed in the "Background" section of the application, "In known systems, the piston is screw-fitted to the driven member. This, however, adversely affects the cost of the device. This solution can also not be used for ready-to-use ampules as the piston is not prepared for a screw connection." (See page 3, lines 14-16).

Thus, Lee not only does not disclose the claimed invention, but also teaches away from the present invention. Lee discloses a system known in the art, the disadvantages of which are exactly described in and overcome by the present invention. Applicant respectfully submits that claim 1 is patentably distinguishable over Lee.

Claims 17 and 26 also recite the features now claimed in claim 1. Claims 2, 6-9, 15-18, and 20-21 which are dependent from claims 1 and 17, respectively, are patentable over Lee for at least the reason stated above.

Claims 1, 2, 6-9, 15 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,143,853 (Abramson). Applicant respectfully traverses the rejection for the following reasons.

Abramson discloses a valve for use with a catheter. More particularly, Abramson discloses a cylindrical valve body made of a male member and a female member telescoped together so as to define opposed annular seats surrounding a through-opening. A disc of rubber having a central domed portion containing an axial slit is mounted between the seats, the male and female members being detented so that the periphery of the disc is pinched thereby displacing rubber radially inwardly to keep the slit normally sealed against flow in either direction. Accordingly, Abramson fails to disclose or teach that the piston is only held in the container by frictional forces, such that advancing movement of the driven member and the piston is controlled to discharge the fluid drug in a dosed manner through the outlet. To the contrary, it appears that Abramson discloses an interlocking mechanism between the piston and

the container. Thus, Applicant respectfully submits that claims 1-2, 6-9, 15 and 26 are patentably distinguishable over Abramson.

Claims 1, 2, 6-9, 15 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cardenas. Applicant respectfully traverses the rejection for the following reasons.

Cardenas discloses a syringe for epidural catheter. More particularly, Cardenas discloses a special epidural catheter syringe, an epidural catheter connector, and a continuous epidural tubing connector to provide mechanical lockouts to prevent epidural anesthetic from being injected intravenously and to prevent medications intended for intravenous use from being injected into the epidural catheter. In column 3, lines 18-21, Cardenas discloses that when the plunger (14) is pulled out of the syringe (10) to draw in liquid, the movable valve member (34) moves to the right until the legs (40) of the valve member (34) abut the first end wall (47) of the valve chamber (36). This is contrary to the claimed invention in that claim 1 recites that the valve is designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column, which is a pressure at the bottom of the fluid column created by the fluid column when the container and catheter are filled and the container is suspended above the injection site to a height allowed by the catheter when extended. In addition, to prevent human errors which are described in the background of Cardenas, Cardenas provides a special epidural catheter syringe which can only inject into a special epidural catheter connector. In column 3, lines 46-51, Cardenas describes that "the syringe (10) cannot be used to inject directly into a patient's vein or into an intravenous line. In fact, the only way liquid can leave the special epidural catheter syringe 10 is by connecting the syringe 10 to a special epidural catheter connect 32, as shown in FIGS. 3 and 4." Accordingly, Cardenas teaches away from having a catheter connected to the outlet of a container which includes a piston, and the catheter having a front end being connected to an injection needle as recited in claim 1. Thus, Applicant respectfully submits that claim 1 is patentably distinguishable over Cardenas.

Claims 17 and 26 also claim the essence of the above discussed features. Applicant therefore respectfully submits that claims 17 and 26, and dependent claims 2, 6-9 and 15, are patentable over Cardenas.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration and the Notice of Allowance are requested.

If a telephone conference would be helpful to advance the application, please contact the undersigned at 612-340-6317.

Respectfully submitted,

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